JUN 12 2002

K021160

Carbon Medical Technologies, Inc.

EXHIBIT 5

510(k) Summary

Submitter's Name, Address, and Date of Submission

Karen E. Peterson
Vice President of Regulatory, Clinical, & QA
Carbon Medical Technologies, Inc.
1290 Hammond Road
St. Paul, MN 55110
Phone: 651-762-2146
Fax: 651-407-1975

Submitted: April 10, 2002

Device Name

Trade Name:	DermMatrix Surgical Mesh
Classification Name:	Surgical Mesh, 21 CFR 878.3300
Common/Usual Name:	Surgical Mesh

Predicate Devices

Carbon Medical Technologies DermMatrix Surgical Mesh [K993459]
Tissue Science Laboratories Permacol (marketed by Bard as Pelvicol) [K992556]
Cook Biotech, Inc. Surgisis Sling [K992159]

Indication for Use

Intended for use in the treatment of hernias where the connective tissue has ruptured or for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support including urethral slings, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, and sacrocolposuspension.

Device Description

DermMatrix is a sterile, chemically treated, pyrogen free, non-perforated porcine skin that has both the epidermal and subdermal sides removed.

Technological Characteristics and Performance

The technological characteristics are identical to the predicate device (DermMatrix). Biocompatibility, bench testing and numerous clinical experiences have demonstrated that the device is safe and effective for its intended use, and that its performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2002

Ms. Karen E. Peterson
Vice President of Regulatory, Clinical
and Quality Affairs
Carbon Medical Technologies, Inc.
1290 Hammond Road
St. Paul, MN 55110

Re: K021160
Trade/Device Name: DermMatrix Surgical Mesh
Regulation Number: 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: April 10, 2002
Received: April 11, 2002

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT 3

Indications for Use Statement

510(k) Number (if known) K021160

Device Name **DermMatrix Surgical Mesh**

Indications for Use

Intended for use in the treatment of hernias where the connective tissue has ruptured
or
for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support including urethral slings, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, and sacrocolposuspension.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021160